



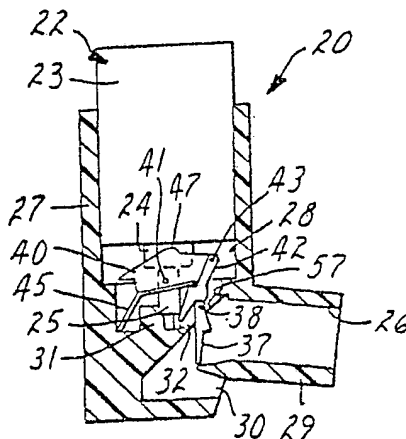
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US84/01721</p> <p>(22) International Filing Date: 25 October 1984 (25.10.84)</p> <p>(31) Priority Application Number: 8328808</p> <p>(32) Priority Date: 28 October 1983 (28.10.83)</p> <p>(33) Priority Country: GB</p> <p>(71) Applicant (for all designated States except US): RIKER LABORATORIES, INC. [US/US]; 3M Center - 225-1S, Saint Paul, MN 55144-1000 (US).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only) : WASS, Anthony, Charles, Lammond [GB/GB]; The Mousehole, Duddington, Stanford, Lincolnshire (GB).</p> <p>(74) Agents: HUEBSCH, William, L. et al.; Office of Patent Counsel, Minnesota Mining and Manufacturing Company, P.O. Box 33427, Saint Paul, MN 55133-3427 (US).</p>		<p>(81) Designated States: AU, FI, JP, US.</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: INHALATION ACTIVATABLE DISPENSERS

## (57) Abstract

An inhalation activatable dispenser (20) for use with an aerosol container (23) in which a latch mechanism releasing vane (37) is pivotably mounted in an air passage (26) between a aerosol outlet valve (24) and a mouthpiece (29), and the latch mechanism cannot be released if force to activate the dispenser (23) is not applied before a patient inhales.



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INHALATION ACTIVATABLE DISPENSERS5     Technical Field

          This invention relates to inhalation activatable dispensers for use with aerosol container assemblies which contain medicaments for inhalation therapy, are pressurized with liquid propellants, and include a metering valve through which a series of metered medicament doses can be dispensed.

Background Art

          Inhalation activatable dispensers for use with aerosol container assemblies of the type described above are well known, their general purpose being to afford proper coordination of the dispensing of a dose of medicament with the inhalation of the patient to allow the maximum proportion of the dose of medicament to be drawn into the patient's bronchial passages. Examples of such dispensers are described in British Patent Specification Nos. 1,269,554, 1,335,378, 1,392,192 and 2,061,116 and United States Patent Nos. 3,456,644, 3,645,645, 3,456,646, 3,565,070, 3,598,294, 3,814,297, 3,605,738, 3,732,864, 3,636,949, 3,789,843 and 3,187,748.

Disclosure of the Invention

          The present invention provides a new and improved inhalation activatable dispenser which is more simple and difficult to misuse than known prior art dispensers.

          According to the present invention, there is provided an inhalation activatable dispenser for use with an aerosol container assembly including a metering valve for dispensing medicament from a container included in the assembly, which valve includes a hollow stem which is movable relative to the rest of the valve and the container



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between an outer closed position to which the stem is biased by a valve spring, and an inner position at which a metered dose of medicament is dispensed from the valve through the stem. The dispenser has a housing formed with a through air passage terminating at a mouthpiece. The housing is adapted to receive the container assembly with the stem in a support block with a through orifice communicating with the air passage and affords the application of a force sufficient to move the valve stem to its inner discharge position in opposition to the valve spring. A latch mechanism is provided comprising a vane disposed in the air passage and movable upon inhalation at the mouthpiece from a blocking position across the air passage at which the latch mechanism is engaged and prevents relative movement between the container and support block in response to the force, and a non-blocking position at one side of the air passage at which the latch mechanism affords such movement in response to the force. The dispenser is operable to dispense aerosol into the air passage by the sequential operations of: applying such a force when the vane is in its blocking position; and inhaling at the mouthpiece, causing movement of the vane to its non-blocking position which releases the lock mechanism and allows the force to move the stem relative to the container to dispense aerosol into the air passage for inhalation by the user.

In the present invention the vane is pivotally mounted in the air passage between the orifice and the mouthpiece. Such location of the vane allows the dispenser to have a small overall size, allows an air inlet for the air passage to be located close to the mouthpiece so that the air inlet and mouthpiece can be closed by a single cover, and separates the container and any moving parts other than the vane from the air passage to minimize the chances of foreign matter being inhaled. Also this position of the vane affords the use of locking means such as a projection on the mouthpiece cover to positively restrain movement of the vane when the dispenser is not in use.



Also in the present invention the latch mechanism includes means which prevent its release to dispense a dose of medicament into the air passage when the vane is in its non-blocking position prior to the application of the force in the dispenser. Thus, it is ensured that the patient cannot commence inhalation too soon before the dose is dispensed and thereby draw an inadequate proportion of the dose into the bronchial passages. Dispensing of a dose only occurs upon inhalation if the force is first applied in the apparatus; however, if the patient inhales first, so that the vane is moved to its non-blocking position, the subsequent application of the force will be inoperable to dispense a dose.

The force to operate the dispenser may be provided by manually pressing the container into the housing of the dispenser or alternatively may be provided by a spring which is manually compressed prior to inhalation through the device to provide a predetermined force to make the apparatus ready for operation by such inhalation.

20

#### Brief Description of Drawing

The invention will be more thoroughly described with reference to the accompanying drawing wherein like reference numerals refer to like parts in the several views and wherein:

25

Figure 1 is a sectional view of a first embodiment of an inhalation activatable dispenser according to the present invention;

Figures 2 through 7 are enlarged fragmentary sectional views showing the operational sequence of the dispenser of Figure 1;

30

Figures 8 through 10 are sectional views of a second embodiment of an inhalation activatable dispenser according to the present invention showing the operational sequence of the dispenser;

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Figure 11 is a sectional view of a third embodiment of an inhalation activatable dispenser according to the present invention shown with a cover on the device closed;

5        Figure 12 is a sectional view of the device of Figure 11 shown with the cover open; and

         Figures 13, 14 and 15 are sectional views of a fourth embodiment of an inhalation activatable dispenser according to the present invention showing its operational  
10        sequence.

#### Detailed Description

         Referring now to Figures 1 through 7 there is  
15        shown a first embodiment of an inhalation activatable dispenser according to the present invention generally designated by the reference numeral 20.

         As is best seen in Figure 1, the dispenser 20 is adapted for use with an aerosol container assembly 22 of the  
20        known kind including a container 23 containing a medicament and liquid propellant, and a metering valve 24 (such as described in U.S. Patent No. 3,598,294 incorporated herein by reference) fixed in one end of the container 23 for  
25        dispensing a metered dose of the medicament from the container 23 through a hollow stem 25 included in the valve 24. The stem 25 is movable relative to the container 23  
         between an outer charging position (to which the stem 25 is biased by a spring in the valve 24) and an inner discharging  
30        position at which a metered dose is discharged through the stem 25.

         The dispenser 20 comprises a housing 27 defining an open ended chamber 28 into which the container assembly 22 may be inserted stem 25 down, a mouthpiece 29, and  
35        a through air passage 26 extending from an inlet opening 30 adjacent the mouthpiece 29 to an outlet through the mouthpiece 29. The housing includes a nozzle block 31 having



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a socket adapted to receive the stem 25, and a through orifice 32 adapted to direct medicament and liquid propellant from the stem 25 into the air passageway 26. Thus upon manual movement of the container 23 toward the block 31 the stem 25 will be moved to its discharging position relative to the container 23 so that medicament is discharged through the orifice 32 into the air passageway 26 toward the mouthpiece for inhalation by the patient. To prevent any escape of the medicament and propellant upwardly out of the nozzle block 31, and to accommodate a certain variation in sizes of stems 25, the dispenser 20 may include a soft seal gasket (not shown) located in the nozzle block 31.

In order to coordinate the dispensing of the medicament with the inhalation of a patient, the dispenser is provided with a latch mechanism including a vane 37 mounted on the housing 27 for a pivotable movement about an axis 38 between a blocking position blocking a portion of the air passageway 26 between the orifice 32 in the nozzle block 31 and the mouthpiece 29 (Figures 1, 2 and 3) and a non-blocking position (Figures 5, 6 and 7) at one side of and not blocking the air passageway 26.

The latch mechanism also comprises a rocker 40 mounted on the housing 27 for pivotal movement about a fulcrum 41, and a catch 42 mounted on the rocker 40 for pivotal movement about an axis 43 spaced from the rocker fulcrum 41. When the dispenser 20 is not in use or in a normal condition (Figures 1 and 2) the container assembly 23 is spaced from the rocker 40 by the internal valve spring in the metering valve 24. The rocker 40 has an integrally formed spring 45 which normally positions the rocker 40 in an initial position at which the catch 42 is held over, but spaced from the vane 37.

To operate the dispenser 20, a user first presses the container 23 into the chamber 28 in the housing 27 until the container 23 contacts the rocker 40 at a point 47 close



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to the fulcrum 41 and rotates the rocker 40 through a small angle about the fulcrum 41 to a retaining position at which further rotation of the rocker 40 or movement of the container 23 is prevented by the engagement between a shoulder 48 of the catch 42 and an edge surface 49 of the vane 37 to produce a cocked condition for the dispenser 20 (Figure 3). The latch mechanism is then engaged to prevent further movement of the container 23 toward the nozzle block 31 by the applied force until inhalation by the user through the mouthpiece 29 moves the vane 37 from its blocking to its non-blocking position to release the latch mechanism and allow the container 23 to be further depressed relative to the stem 25 held in the block 31 to dispense a dose of medicament.

One position of the vane 37 and latch 42 in the latch mechanism during such inhalation is shown in Figure 4. The vane 37 has begun to rotate counter-clockwise due to the reduced air pressure in front of it caused by the inhalation. The shoulder 48 on the catch 42 is a true arc about its pivot axis 43, and the edge surface 49 of the vane 37 is a true arc about its pivot axis 38 so that frictional contact between the edge surface 49 of the vane 37 and the shoulder 48 of the catch 42 causes the rotating vane 37 to pivot the catch 42 clockwise about its axis 43. Because both contact surfaces are true arcs, no pivotal movement of the rocker 40 can occur during this stage. The arcuate shoulder 48 of the catch 42, however, terminates at a heel 51. Once the heel 51 reaches a line between the axes 38 and 43, the latch mechanism can no longer prevent the downward movement of the container 23 due to the pressure applied by the user. The edge surface 49 of the vane 37 rotates onto and along a side contact surface of the catch 42 which is a true arc about the rocker fulcrum 41 since the rocker 40 carries a second spring 53 which then biases the catch 42 into contact with the vane 37 as the rocker 40 pivots further around the fulcrum 41 to a non-retaining position and allows the





container 23 to move further into the chamber 28 to provide a dispense condition for the dispenser 20 (Figure 6).

In order that movement of the container 23 into the chamber 28 will assist in lifting the vane 37, the vane 37 is provided with a pair of projecting ledges that successively and respectively are engaged by the catch 42 and the rocker 40 to push the vane 37 fully to one side of the air passageway 26 and hold it clear of the air passage portion from orifice 32 to the mouthpiece 29. The metering valve 24 dispenses (Figure 6) a metered dose of medicament during the final part of the downward movement of the container 23 and during an early part of the inhalation cycle of the user to ensure that a maximum portion of the dose enters the user's bronchial passages.

To avoid undue noise caused by the contact between the vane 37 and the housing 27, the movement of the vane 37 to its non-blocking position is damped by contact with a flexible web 57 integrally formed with the housing 27 and by the expulsion of air from a pocket defined between the web 57 and an adjacent face of the vane 37.

When the user releases the manual pressure on the container 23, it moves away from the nozzle block 31 under the influence of the internal valve spring. The rocker 40 is then free to rotate counter-clockwise to its normal position (Figure 2) under the influence of the rocker spring 45. The vane 37 should then fall freely into a vertical position under the influence of gravity but, in the event that it adheres to the housing wall, a peg on the moving rocker 40 will engage an arm on the vane 37 to break such adhesion and allow the vane 37 to fall. The catch 42 is returned to the position shown in Figure 2 by the action of the rocker spring 45, and the operating mechanism is now again in its normal condition, ready for a repeat of the dispensing operation.

The operating mechanism, as described above, is designed to ensure that the dose is delivered during the



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early part of the inhalation cycle. It also includes means for preventing incorrect use of the dispenser 20, such as by inhaling through the mouthpiece 29 before force is applied to press the container 23 into the housing 27, or by holding  
5 the dispenser 20 in an inverted position.

In the former case, inhalation will cause the vane 37 to move to its non-blocking position but without simultaneously pivoting the catch 42, since the catch 42 will only be pivotable if it has first been brought into  
10 contact with the vane 37 by the application of force to move the container 23. Once the vane 37 has fully moved to its non-blocking position, if the container 23 is subsequently depressed, no further counter-clockwise movement of the vane 37 is possible to rotate the catch 42. The catch 42 is then  
15 retained by the edge surface 49 of the vane 37 and the mechanism cannot be released so that no dose of medicament can be discharged.

In the latter case, holding the dispenser 20 in an inverted position is undesirable in that the metering valve  
20 24 cannot be relied upon to dispense a full dose. The mechanism will not operate in the inverted position because the vane 37 will immediately fall under gravity into the same horizontal non-blocking position to which it is moved by inhalation. The latch mechanism will therefore be unable  
25 to be released for the same reason described above where inhalation occurs before force is applied to the container 23.

Figures 8, 9 and 10 illustrate an alternate construction for an inhalation activatable dispenser 70  
30 according to the present invention for use with the container assembly 22 and which is operated in the same manner as the device 20, but in which a latch mechanism for resisting movement of the container 23 toward a nozzle block 71 on a housing 72 for the dispenser 70 comprises only a  
35 vane 74 pivotably mounted on the housing 72 about an axis 75 for movement between blocking and non-blocking positions.



corresponding in position and function to those of the vane 37 in the device 20, and a roller 77 rotatably carried at the end of an arm 78 pivotably mounted on the housing 72 at its end opposite the roller 77. With the vane 74 in its blocking position the roller 77 contacts a vane surface 79 which is circular about the axis 75 and is disposed so that pressure against the surface 79 caused by pressure against the opposite side of the roller 77 will cam the vane 74 to its non-blocking position and will prevent movement of the roller 77 out from under the container 23. (Figure 8). Movement of the vane 74 to its non-blocking position upon inhalation through a mouthpiece 80 on the device 70, however, will cause the roller 77 to move around an end of the vane 74 and onto an edge surface 81 of the vane 74 that will allow the roller 77 to move along the edge surface 81 of the vane 74 and from beneath the container 23 end to allow the container 23 to move relative to the nozzle block 71 (Figure 10) so that the valve assembly discharges a metered dose of medicament and propellant through an orifice 83 in the block 71 into the air passageway 76 toward the mouthpiece 80.

While in the dispensers 20 and 70 the nozzle block 31 and fulcrum 41 for the rocker 40 are fixed on the housings 27 and 72 and the container 23 is movable within the housings 27 and 72 to produce discharge of a dose of medicament from the metering valve 24, it is also possible, as is illustrated in the dispenser embodiment 90 shown in Figures 11 and 12 to fix the container 23 within a housing 91 for the dispenser 90 and mount a nozzle block 92 and a fulcrum 93 for a rocker 94 similar to the rocker 40 on a member 95 which is movable relative to the rest of the housing 91. The use of a catch 96 similar to the catch 42 pivotably mounted at an axis 97 on the rocker 94 and a vane 98 similar to the vane 37 pivotably mounted on the housing 91 in a through air passageway 99 defined in the housing 91 then affords operation of the dispenser 90 in a manner



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similar to the operation of the dispenser 20 except that the force applied to operate the device 90 is applied to the member 95 centrally toward the container assembly 22 either manually, or, as illustrated, by a coil spring 100 that may  
5 be compressed by pivotal movement of a cover 102 for the device 90 from a closed position (Figure 11) to an open position (Figure 12) around a pin 103, which cover 102 and coil spring 100 arrangement has the advantage of being easily operable and providing a uniform force to drive the  
10 dispenser 90.

The device 90 as illustrated, may also include a second spring 105 as a supplement to the internal spring in the metering valve 24 to help hold the container assembly 22 and rocker 94 apart when the dispenser is in its normal  
15 position. This permits the accommodation by the dispenser of a wider range of nozzle stem lengths, and provides for a discernible degree of initial movement of the member 95 to the cocked position for the dispenser. The outward force exerted by this second spring will of course be sufficiently  
20 small to be overcome by the coil spring 100.

Figures 13, 14 and 15 illustrate an embodiment 110 of a dispenser according to the present invention which function like the dispenser 90, and like the dispenser 90 fixes the container 23 within a housing 111 for the  
25 dispenser 110 and mounts a nozzle block 112 and a fulcrum 113 for a rocker 114 similar to the rocker 40 on a member 115 which is movable relative to the rest of the housing 111. Also included are a catch 116 similar to the catch 42 pivotably mounted at an axis 117 on the rocker 114 and a  
30 vane 118 similar to the vane 37 pivotably mounted on the housing 111 in a through air passageway 119 defined in the housing 11 from an inlet 120 to a mouthpiece 121. Like the dispenser 90, the dispenser 110 operates in a manner similar to the operation of the dispenser 20 except that the force  
35 applied to operate the dispenser 110 is applied to the member 115 toward the container assembly 22 by an L-shaped



leaf spring 123 that may be compressed by movement of a cover 124 for the device 90 from a closed position (Figure 13) to an open position (Figure 14). As illustrated, opening of the cover 124 causes a spur gear 125 fixed on the cover 124 to move along a rack 126 formed on the housing 111 so that a cam end 127 on the cover 124 engages and presses the spring 123 toward the container 23 to provide the force needed to operate the dispenser 110.

In any of the embodiments, provision may be made for the adjustment of the position of the catch at initial contact with the vane, whereby the degree of rotation of the vane required to roll the catch over the heel and thus permit the vial to fire may be varied. An adjuster in the form of a screw projecting through the nozzle block may be arranged to bear on the tail end of the catch whereby the initial angular position of the catch may be altered by varying the projecting length of the screw.



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## CLAIMS:

1. An inhalation activatable dispenser for use with an aerosol container having a valve for dispensing aerosol from an outlet in the container, the valve having a hollow stem which is movable relative to the container between an outer closed position and an inner discharging position of the valve, said dispenser including a housing having an air passage therethrough terminating at a mouthpiece, the housing being adapted to receive such an aerosol container, having a support block with a socket adapted to receive said stem and a through orifice communicating between said socket and said air passage, and said dispenser including a latch mechanism movable between an engaged position preventing the movement of said container and said support member toward each other upon the application of a force to bias the container and said support block toward each other, and a release portion affording movement of said container and said support block toward each other in response to said force to move said stem to its inner discharge position, said latch mechanism comprising a vane mounted in said air passageway and movable from a blocking to a non-blocking position with respect to said passageway to move said latch mechanism from said engage to said release position so that inhaling at the mouthpiece causes movement of said vane to its non-blocking position which allows said cocking force to move said stem relative to the container to its inner discharging position to dispense aerosol into the air passage for inhalation by the patient, wherein said vane is pivotably mounted in said air passageway between said orifice and said mouthpiece.

2. A dispenser according to claim 1 wherein said latch mechanism includes means to prevent movement of said latch mechanism to said release position when said vane is



in said non-blocking position prior to application of said force to bias the container and said support block toward each other.

5                   3. A dispenser according to claim 1 in which  
said latch mechanism comprises a rocker member pivotable  
with respect to the dispenser about a fulcrum and a catch  
pivotably mounted on said rocker about an axis remote from  
10   edge surface opposite said axis adapted to engage an  
arcuate drive surface on said vane, and a side surface  
disposed so that movement of said vane from said blocking  
to said non-blocking position by driving engagement between  
said surfaces pivots said latch to afford movement of said  
15   side surface along said vane and pivoting of said rocker  
about said fulcrum to afford movement of said support block  
and container toward each other.

                  4. A dispenser according to claim 1 wherein said  
20   support block is fixed on said housing and said housing  
affords manual application of said force between said  
container and said housing.

                  5. A dispenser according to claim 1 wherein said  
25   container is fixed on said housing, said support block is  
fixed on a member movable with respect to said housing, and  
said dispenser comprises a spring adapted to be compressed  
and apply said force between said container and support  
block.

30                   6. A dispenser according to claim 5 comprising a  
cover for said mouthpiece pivotably mounted on said housing  
and adapted to compress said spring upon movement of said  
cover from closed to an open position.

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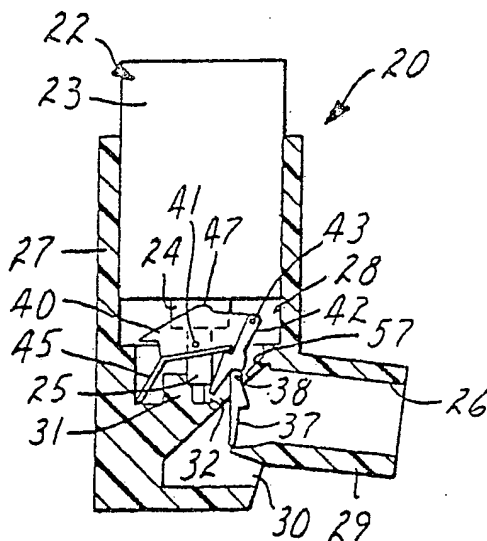


FIG. 1

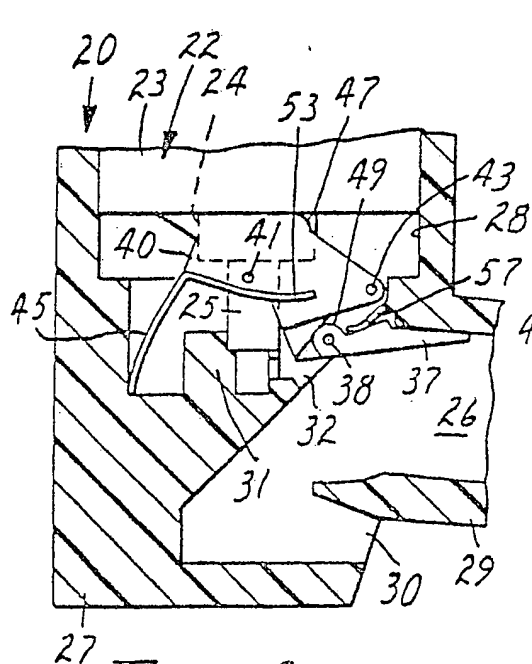


FIG. 6

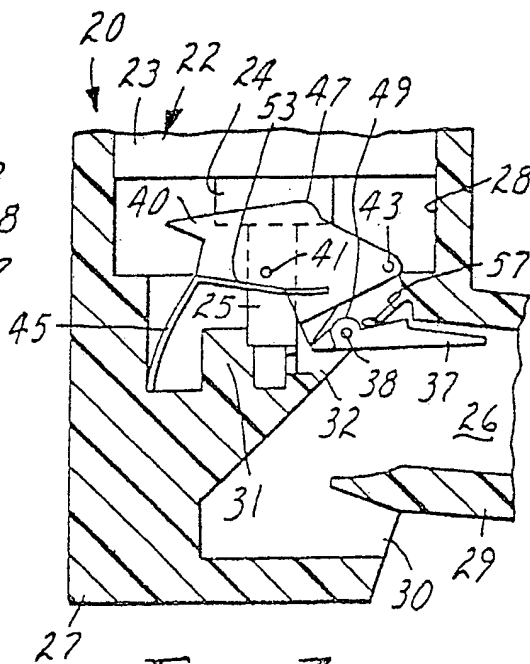


FIG. 7



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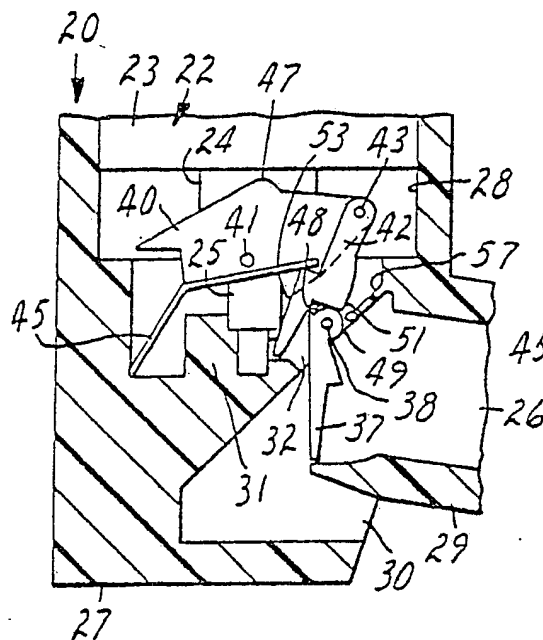


FIG. 2

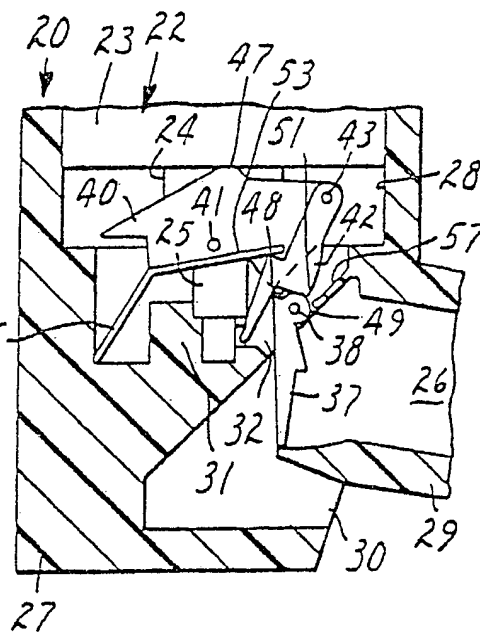


FIG. 3

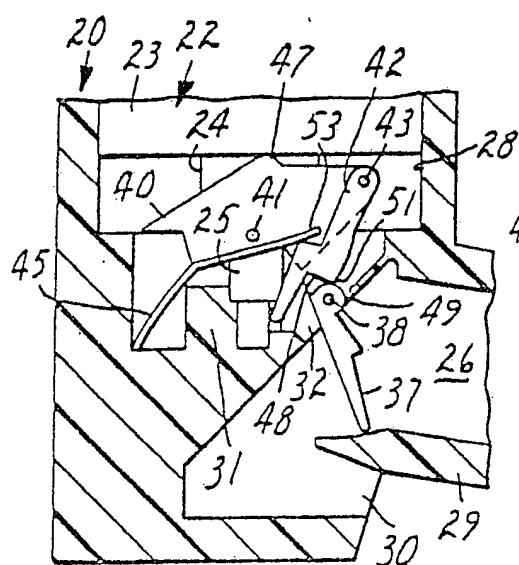


FIG. 4

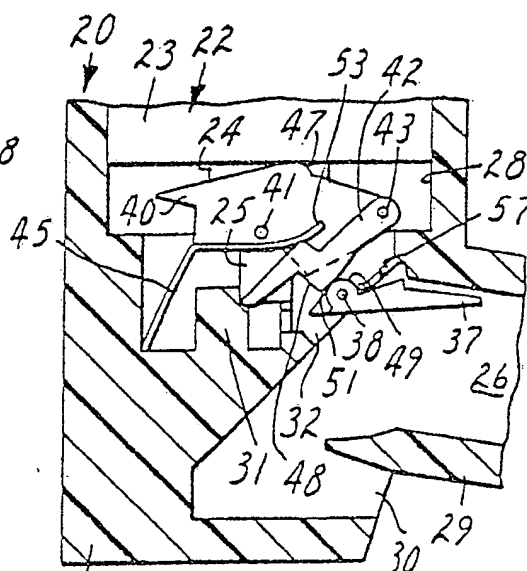


FIG. 5

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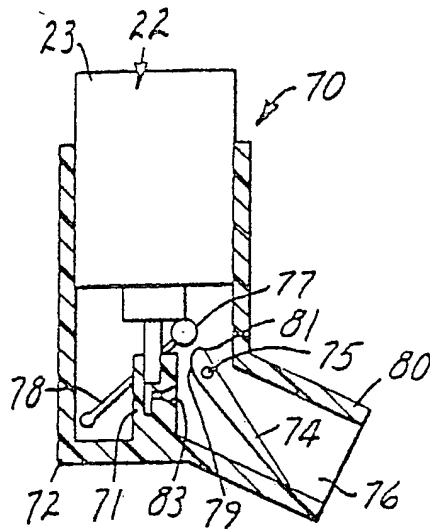


FIG. 8

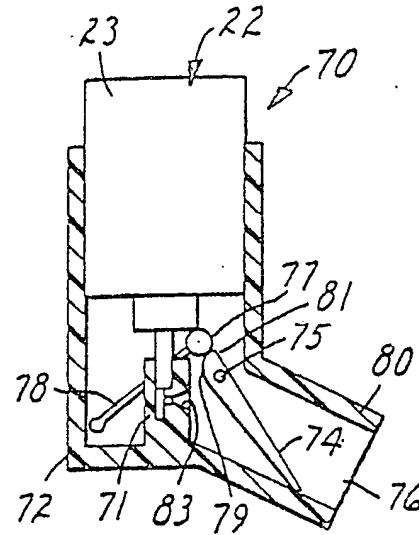


FIG. 9

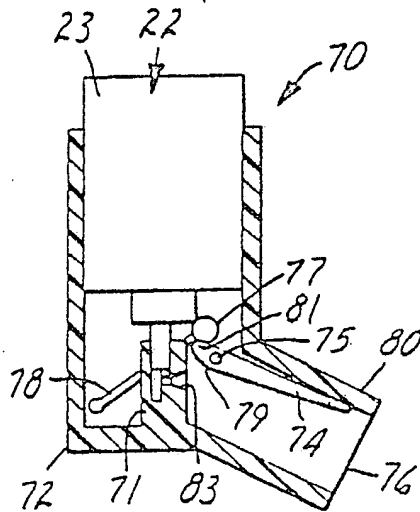


FIG. 10

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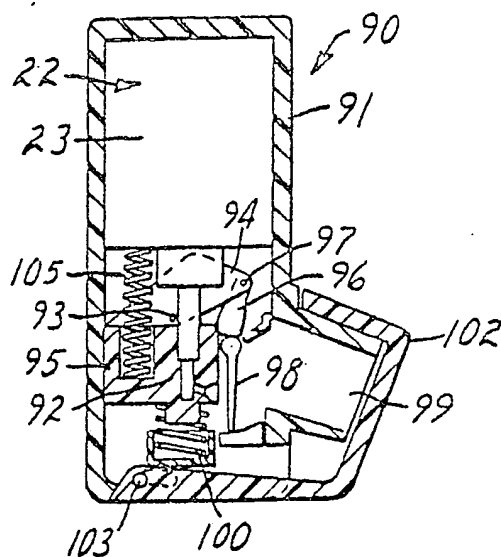


FIG. 11

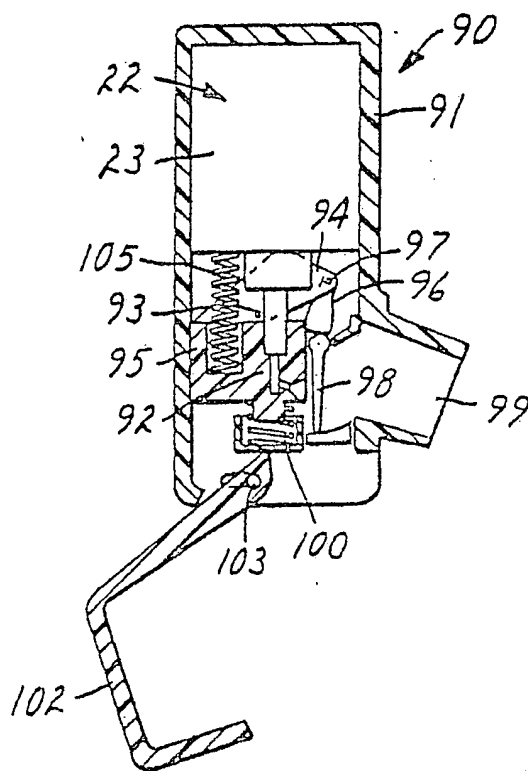


FIG. 12

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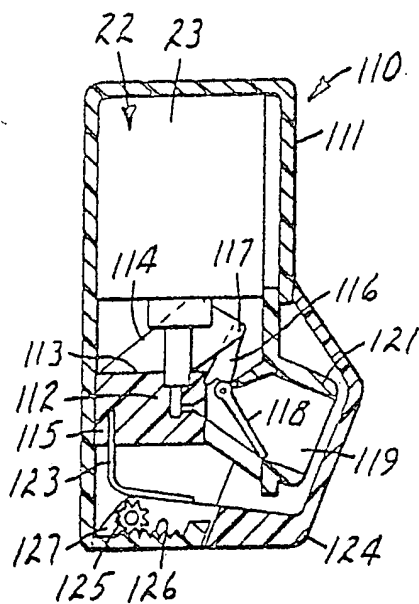


FIG. 13

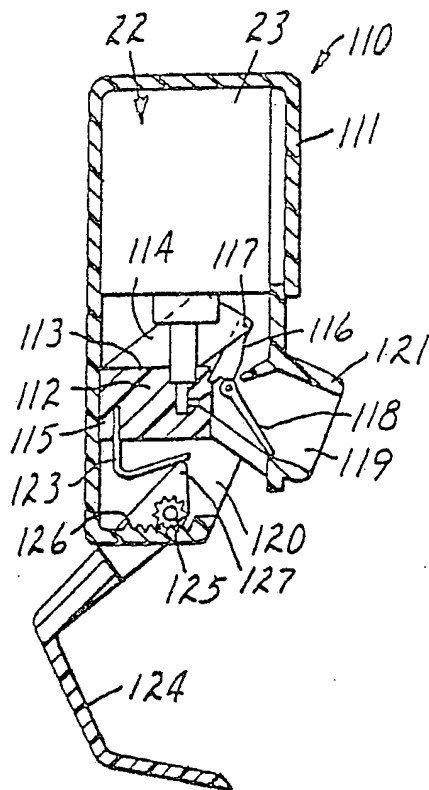


FIG. 14

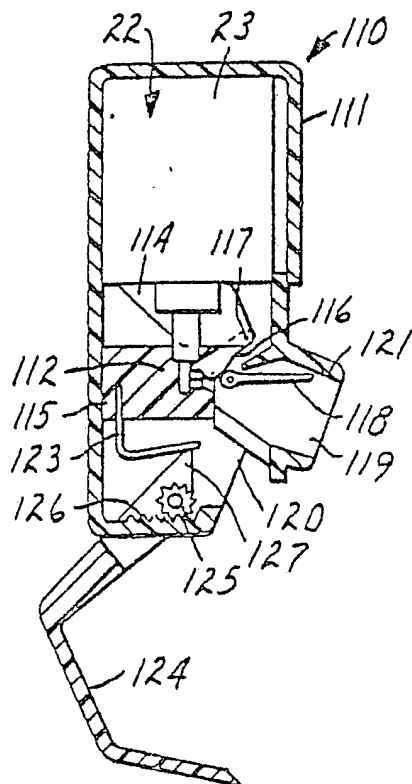


FIG. 15

SUBSTITUTE SHEET



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 84/01721

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC <sup>4</sup> : A 61 M 15/00; B 65 D 83/14		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System <sup>1</sup>	Classification Symbols	
IPC <sup>4</sup>	A 61 M; B 65 D	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>		
Category <sup>6</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	DE, A, 3040641 (QUADE) 25 May 1982 see page 3, paragraph 5 - page 5, paragraph 1; figures 1-4	1,4
Y	--	2,3,5,6
Y	FR, A, 2069300 (RIKER LAB. INC.) 3 September 1971 see page 10, line 10 - page 11, line 6; figures 1,4,12 (cited in the application)	2,3
Y	US, A, 3789843 (ARMSTRONG) 5 February 1974 see abstract; figures 1,2,6,7 (cited in the application)	5,6
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<p>* Special categories of cited documents: <sup>10</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Δ" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
11th February 1985	11 MARS 1985	
International Searching Authority	Signature of Authorized Officer	
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